PSJ3

Exhibit 175

January 23, 2009

Frank Torti, M.D., Acting Commissioner
White Oak Complex Building
109083 New Hampshire Avenue
Building 1, Room 217
Silver Spring, MD 20993

Dear Acting Commissioner Torti:

The undersigned organizations write to express our concerns regarding the possible proliferation of Risk Evaluation and Mitigation Strategies (REMS) for opioid analgesic medications and to request a meeting between stakeholders and the Food and Drug Administration (FDA) to help design a REMS program for these products that meets the needs of patients, health care providers, and the Agency.

Concerns:

During the November 13 and 14, 2008 Advisory Committee meetings regarding the pending applications for two investigational pain medications, concern was expressed by a number of public participants and committee members about the potential for multiple, overlapping, product-specific REMS requirements that could overwhelm patients, prescribers and pharmacists and, therefore, interfere with appropriate patient care. Inconsistencies and differences between programs with similar elements have been particularly troublesome. Moreover, because of the widespread use of opioid medications, and the correspondingly large number of specialists and general practitioners prescribing and pharmacists dispensing these medications, a patchwork of product-specific, DEA schedule-specific, dose-specific, or formulation –specific REMS is neither practical nor feasible. Such a patchwork approach is bound to lead to diminished care for people who would benefit from these medications.

Additionally, imposition of restricted distribution requirement on one drug or group of drugs has the potential to systematically increase prescriptions for other similar drugs that are not subject to the same requirements. Thus, piecemeal application of different REMS for different opioid analgesic medications may simply shift, without actually mitigating, the various risks associated with all the medications in this class, while simultaneously denying some patients' access to the medication that their prescriber recommends. For example, as noted in the FDA's briefing materials for the Advisory Committee hearing on November 14, 2008, historically, when

availability of one drug with abuse potential has been curtailed, abuse of another similar drug generally increases. In addition to the impact on nonmedical use, uneven application of restricted distribution requirements among opioid analgesics could mean that patients do not receive the drug most suitable to treat their condition, either because the available prescriber or pharmacy is not enrolled in the relevant REMS program, or because the patient requires therapy immediately and cannot wait for completion of a lengthy REMS registration process.

Request:

In the case of opioid analgesics, there are common risks to be managed including determining the safe dosage; the risk of opioid misuse; abuse and diversion; the safe storage and disposal; the management of side-effects; the potential for accidental or intentional overdose; and how to discontinue usage. There are also instances of product-specific risks that must be addressed to maximize safety. Developing a REMS program which addresses the common risks in a uniform fashion and the product specific risks without creating burdens for prescribers, pharmacists, and patients is a goal we endorse. We request that the FDA provide all affected stakeholders with the opportunity to contribute to the development of this program and to provide information and comment upon any proposed uniform opioid-class REMS prior to implementation. The new FDA Amendments Act of 2007 REMS provisions specifically provide the FDA with the authority to consider and address REMS as they pertain to a class of drugs (21 U.S.C. § 355-1(h)(7)). These provisions contemplate that in cases of serious risks related to a pharmacological class, the FDA will meet with the affected sponsors, stakeholders, and Advisory Committees to develop a regulatory plan to address the class-wide risks. We believe these procedures are well suited to developing a REMS program that addresses the risks of opioid analgesics and invite the FDA to collaborate with key stakeholders—prescribers, pharmacists, patients, wholesalers, and those who advocate for appropriate and effective pain care.

All of the undersigned, representing patients, prescribers, pharmacists, physicians, nurses, pain educators, pain researchers, policy experts, ethicists, and manufacturers, are eager to participate in this process. We, therefore, request a meeting with the appropriate FDA officials in order to discuss the many issues surrounding the design and implementation of a successful opioid analgesic REMS program---one that addresses risks and protects access to these medications for people who need them. We look forward to constructively assisting the FDA in striking the correct balance between mitigating the risks associated with this class of drugs, including limiting misuse, diversion, and abuse of opioids while maintaining access to these important medications and ensuring appropriate care of patients.

We look forward to hearing from you in the near future. Our primary contact to arrange for this initial meeting is Will Rowe, Chief Executive Officer of the American Pain Foundation, who will facilitate all communication and activity for the undersigned. Mr. Rowe can be reached at 201 North Charles Street, Suite 710, Baltimore MD, 21201, phone 410-783-7292, Ext. 225, and at wrowe@painfoundation.org.

Sincerely,

Abbott
Alliance of State Pain Initiatives
American Academy of Pain Management
American Academy of Pain Medicine
American Cancer Society
American Chronic Pain Association
American Pain Foundation
American Pain Society
American Pharmacists Association
American Society of Health-System Pharmacists
American Society of Pain Educators
American Society for Pain Management Nursing
Center for Practical Bioethics
Collegium Pharmaceuticals
Ehlers Danlos National Foundation
Endo Pharmaceuticals
Federation of State Medical Boards
Maryland Pain Initiative
National Hospice and Palliative Care Organization
National Pain Foundation
Pain and Policy Study Group
Purdue Pharma
Reflex Sympathetic Dystrophy Association
US Oncology

cc: Bob Rappaport, M.D., Janet Woodcock, M.D, Robert J. Temple, M.D., Gerald Dal Pan, M.D.